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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JUSTIN M. CRANK

Appeal 2009-0388[1]
Application 10/647,613
Technology Center 3700

Decided:[2] May 14, 2009

Before RICHARD M. LEBOVITZ, FRANCISCO C. PRATS, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

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[1] Boston Scientific Scimed, Inc., is the real party in interest (App. Br. 3).
[2] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to medical devices. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The claimed invention "pertains to intra-lumenal medical devices, such as guidewires, catheters or the like, wherein in use, they are inserted into vascular lumens or other body lumens for treatment and diagnosis" (Spec. 1). The claimed medical devices include "a coil having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a wire" (*id.*).

Appellant's Figure 1, reproduced below, "is a perspective view of an example coil" (*id.* at 3):

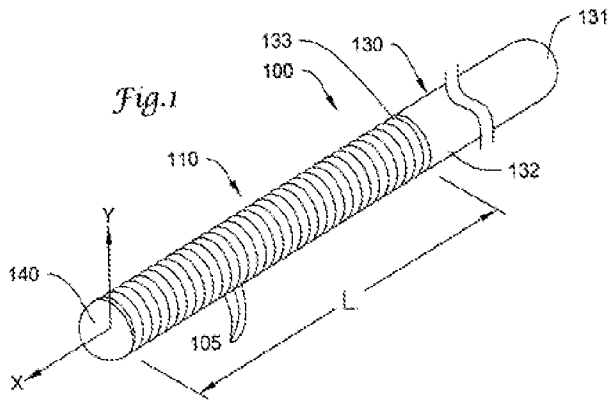

Figure 1 shows coil 110, "incorporated into an elongate medical device 100 . . . [which] may include an elongate shaft or core 130. The elongate shaft or core 130 can have a proximal end 131 and an opposing distal end 132" (*id.* at 5). As seen in Figure 1, "[t]he coil 110 may have a plurality of windings 105 that form a coil length L" (*id.*).

As also seen in Figure 1, "[i]n some embodiments, the coil 110 can be wrapped [around the core] in a helical fashion by conventional winding techniques" (*id.* at 7). Further, "[t]he coil 110 has a longitudinal axis x, and a radial axis y orthogonal to the longitudinal axis x as indicated by coordinate axis in Figures 1-8. The longitudinal axis x is parallel to the length L of the coil 110" (*id.*).

Claims 1, 2, 5, 7, 9-11, 14, 16, 18, 19, 21, 22, 25, 26, 28, 29, and 32 stand rejected and are on appeal (App. Br. 3). Claims 1, 10, 19, and 26, the appealed independent claims, are representative and reads as follows:

> 1. A medical device comprising:
> a coil having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a wire, the wire comprising:
> (a) a cross-section with a centroid;
> (b) a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil; and
> (c) a moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil, wherein the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil.
>
> 10. A medical guidewire comprising:
> (a) an elongated shaft including a proximal region having a first outer diameter and a distal region having a second outer diameter that is smaller than the first outer diameter;
> (b) a coil member connected to the elongated shaft at the distal end of the proximal region and extending from the distal end of the proximal region over at

least a portion of the distal region, the coil member having an inner diameter that is greater than the second outer diameter, wherein the coil has a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a wire, the wire comprising:

(i) a cross-section with a centroid;

(ii) a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil; and

(iii) a moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil, wherein the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil.

19. A medical device comprising:

a coil having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a composite wire, the composite wire comprising:

(a) a cross-section with a centroid, a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis;

(b) a first material having a first Young's Modulus at the centroid; and

(c) a second material having a second Young's Modulus further away from the centroid along the wire radial axis; wherein the second Young's Modulus is greater than the first Young's Modulus.

26. A medical guidewire comprising:

(a) an elongated shaft including a proximal region having a first outer diameter and a distal region having a second outer diameter that is smaller than the first outer diameter;

(b) a coil member connected to the elongated shaft at the distal end of the proximal region and extending from the distal end of the proximal region over the distal region, the coil member having an inner diameter that is greater than the second outer diameter, wherein the coil having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a composite wire, the composite wire comprising:

(i) a cross-section with a centroid, a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis;

(ii) a first material having a first Young's Modulus at the centroid; and

(iii) a second material having a second Young's Modulus further away from the centroid along the wire radial axis; wherein the second Young's Modulus is greater than the first Young's Modulus.

The Examiner cites the following documents as evidence of unpatentability:

Dobson	US 5,724,989	Mar. 10, 1998
Samson et al.	US 5,827,201	Oct. 27, 1998

The following rejection is before us for review:

Claims 1, 2, 5, 7, 9-11, 14, 16, 18, 19, 21, 22, 25, 26, 28, 29, and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Samson in view of Dobson (Ans. 3-7).[3]

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[3] Examiner's Answer mailed May 23, 2007. We note that the Examiner has rejected all of the pending claims using two somewhat overlapping rationales, one of which was designated as a new ground of rejection (*see* Ans. 4). While we will evaluate the merits of both rationales presented by

OBVIOUSNESS

ISSUE

The Examiner finds that Samson discloses the device and guidewire of claims 1 and 10, including a coil made of a wire that has a moment of inertia with respect to the coil's longitudinal x axis that is greater than the moment of inertia with respect to the coil's radial y axis (*see* Ans. 5). The Examiner finds that Samson meets that limitation because Samson's wire has a cross section which "is a polygon, i.e. not symmetric, and more material is distributed away from the longitudinal axis (the x-axis) without less material being distributed away from the radial axis (the y-axis)" (*id.* at 5-6 (citing App. Br. 13-15)).

The Examiner concedes that Samson differs from the claims in that Samson does not use a composite wire as a coil element as recited in claims 19 and 26, and cites Dobson to meet the limitation (Ans. 3-4). Specifically, the Examiner finds that Dobson discloses a medical device with a coil composed of a composite wire with a first material, stainless steel, at the centroid, and a second material, tungsten, away from the centroid along the radial axis (*id.* at 6).

The Examiner finds that Dobson's wire meets the limitations of claims 19 and 26 because the stainless steel at the wire's centroid has a Young's Modulus which is less than the Young's Modulus of the tungsten material (*id.*). Based on the references' teachings, the Examiner concludes that a person of ordinary skill in the art would have considered it obvious to modify Samson's guidewire "with the medical guidewire as taught by

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the Examiner, because the same claims were rejected over the same references, we will not treat the rejections as separate rejections.

Dobson for the purpose increasing the efficacy of the medical guidewire to navigate tortuous vasculature thereby increasing patient safety during advanced surgical procedures by configuring the material and mechanical properties of medical guidewire" (*id.* at 7).

Appellant contends that Samson does not meet the limitations in claims 1 and 10 regarding the wire's moment of inertia (Reply Br. 5). Specifically, Appellant argues, for the moment of inertia to be greater along the x axis than the y axis, as required by claims 1 and 10, the wire must have less material along the x axis than the y axis (*see id.*).

In contrast, Appellant urges, the ribbons coiled about Samson's device have a greater amount of material along the x axis than the y axis (*id.*). Appellant further contends that Dobson's wire does not remedy Samson's shortcoming in this respect because Dobson's composite wire is symmetrical and therefore the moments of inertia with respect to the x and y axes will be the same, contrary to the requirements of claims 1 and 10 (App. Br. 12-13).

With respect to claims 19 and 26, Appellant urges that the claimed configuration of materials "may give the coil increased torsional rigidity without sacrificing the flexibility of the coil, thereby increasing the torqueability/flexibility ratio of the coil" (Reply Br. 7 (citing Spec. 15:16-28)). In contrast, Appellant argues, because the second material in Dobson's wire is distributed equally in all directions about the centroid "the torqueability/flexibility ratio of the [coil] is not increased" (*id.*).

In view of the positions advanced by Appellant and the Examiner, the issue with respect to this rejection is whether the Examiner erred in finding that Samson and Dobson would have suggested a coil member encompassed by claims 1, 10, 19, and 26 to a person of ordinary skill in the art.

FINDINGS OF FACT

1. Claim 1 recites a medical device that has a coil with a longitudinal axis and a radial axis orthogonal to the longitudinal axis. The coil is formed from a wire that has a cross-section with a centroid.

Claim 1 limits the wire to one in which "the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil."

2. Claim 10 recites a medical guidewire made, essentially, of an elongated shaft covered at least in part by a coil formed from a wire with the properties recited in claim 1.

3. Appellant's Figure 3, reproduced below, "is a cross-sectional view of an example coil 300" having features that we conclude are encompassed by claim 1 (Spec. 12):

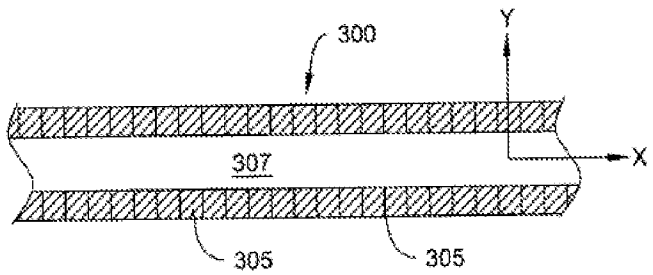

Fig.3

Figure 3 shows "coil 300 [which] has a longitudinal axis x, and a radial axis y orthogonal to the longitudinal axis x and a lumen 307. The coil 300 is formed from a wire 305 having a cross-section. The coil 300 coordinate system can be transposed directly onto the wire 305 cross-

section" (Spec. 12). As seen in Figure 3, "[t]he wire 305 cross-section is shown as rectangular" (*id.*).

4. Appellant's Figure 4, reproduced below, "is a cross-sectional view of an example wire 400" encompassed by claims 1 and 10 (Spec. 12):

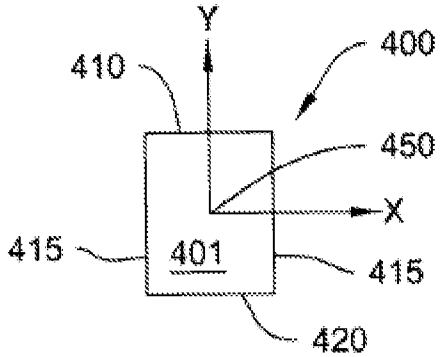

Fig.4

Figure 4 shows the wire's cross-sectional area 401, which has a "centroid 450[,] a longitudinal axis x parallel to the coil longitudinal axis, and a radial axis y parallel to the coil radial axis and orthogonal to the longitudinal axis x. The centroid 450 may be a point which defines the geometric center of a cross-sectional surface area or object" (Spec. 12). As seen in Figure 4, "[t]he longitudinal axis x intersects the radial axis y at the centroid 450" (*id.*).

5. The Specification discloses that the wire's cross sectional area has a moment of inertia, termed I_x, with respect to an axis running through the centroid and parallel to the longitudinal x axis (Spec. 12-13).

6. The Specification discloses that the wire's cross sectional area has a moment of inertia, termed I_y, with respect to an axis running through the centroid and parallel to the radial y axis (*id.* at 13).

7. These moments of inertia are defined, respectively, by the integrals $I_x = \int y^2 dA$ and $I_y = \int x^2 dA$, "in which x and y are the coordinates of the differential elements of area dA" (*id.*).

8. Regarding the wire cross-section shown in Figure 4, "[t]he moment of inertia I_x with respect to an axis running through the centroid 450 and parallel to the longitudinal axis x of the coil is greater than the moment of inertia I_y with respect to an axis running through the centroid 450 and parallel to the radial axis y of the coil" (*id.*).

9. Thus, referring again to Figure 4, for a coiled wire with a rectangular cross section to have a moment of inertia I_x greater than the moment of inertia I_y, the longitudinal walls parallel to the x axis must be shorter than the radial walls parallel to the y axis (*id.*).

10. Appellant's Figure 5, reproduced below, "is a cross-sectional view of an example wire 500 forming a coil" (*id.*):

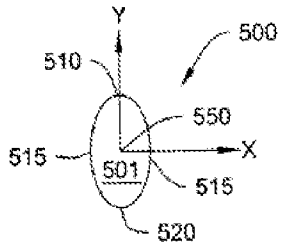

Fig.5

Figure 5 shows elliptical cross sectional area 501 with centroid 550, "a longitudinal axis x parallel to the coil longitudinal axis, and a radial axis y parallel to the coil radial axis and orthogonal to the longitudinal axis x" (*id.*).

11. As also seen in Figure 5, "[t]he moment of inertia I_x with respect to an axis running through the centroid 550 and parallel to the longitudinal axis x of the coil is greater than the moment of inertia I_y with respect to an axis

running through the centroid 550 and parallel to the radial axis y of the coil" (*id.*). Thus, "[t]he cross-sectional area 501 shown corresponds to an ellipse having longer radial walls 515 than longitudinal walls 510, 520" (*id.*).

12. Claim 19 recites a medical device that has a coil with a longitudinal axis and a radial axis orthogonal to the longitudinal axis.

The coil is formed from a composite wire that has a cross-section with a centroid. The wire's cross-section has a longitudinal axis parallel to the coil longitudinal axis and a radial axis parallel to the coil radial axis.

The composite wire is made from a first material having a first Young's Modulus at the centroid and a second material having a second Young's Modulus further away from the centroid along the wire radial axis. The second Young's Modulus must be greater than the first Young's Modulus.

13. Claim 26 recites a medical guidewire made, essentially, of an elongated shaft covered at least in part by a coil formed from a wire with the properties recited in claim 19.

14. Appellant's Figure 7, reproduced below, shows a cross-section of a composite wire that meets the limitations of claims 19 and 16:

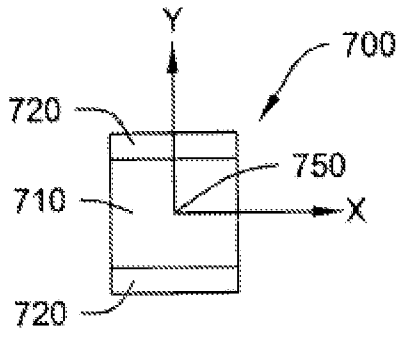

Fig.7

Figure 7 shows "first material 710 having a first Young's Modulus . . . disposed at the centroid 750 and a second material 720 having a second Young's Modulus . . . disposed further away from the centroid 750 than the first material 710 along the wire radial axis y" (Spec. 14).

15. The Specification discloses that "[t]he second material's 720 Young's Modulus is greater than the first material's 710 Young's Modulus. Thus, the second material 720 is stiffer than the first material" (*id.*).

16. Samson discloses "a guidewire suitable for introduction into the vasculature of the brain" (Samson, col. 4, ll. 8-9).

17. Samson discloses:

> The guidewire desirably is of four particular components and may comprise others. The first component is a core wire of either a super-elastic alloy, a stainless steel, or a composite of both. The second component is a super-elastic ribbon braid which surrounds a portion of the flexible core wire and changes the mechanical properties of the device. The third component is an optional, but desirable, distally located coil of a soft and usually radio-opaque material terminated by an adhesive bead. The fourth component is a polymeric layer placed over some or all of the assembled metallic components which layer may be coated with an additional lubricious polymer coating.

(Samson, col. 4, ll. 10-21.)

18. Figure 1 of Samson is reproduced below:

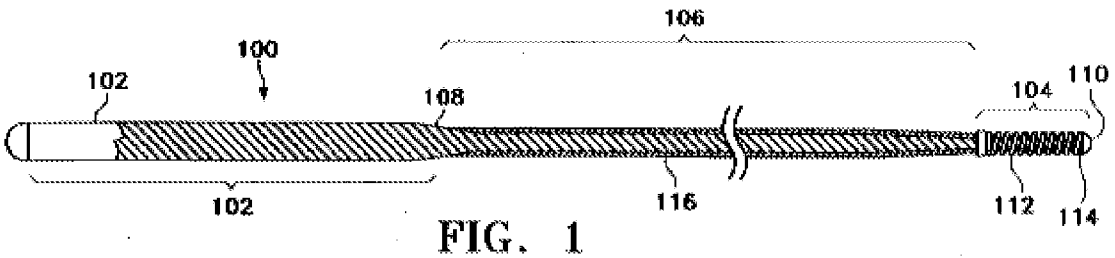

FIG. 1

Figure 1 shows guidewire 100 "made up of the wire core formed of a flexible torqueable wire filament material . . . [with] distal end section (104) of the core wire typically has an atraumatic distal tip (110), a fine wire coil (112), and at least one adhesive joint (114)" (Samson, col. 5, ll. 12-30).

19. Samson discloses that wire coil 112 "may be radio-opaque and made from materials including but not limited to platinum and its alloys. The atraumatic distal tip (110) may be radio-opaque to allow knowledge of the position of the coil (112) during the process of inserting the catheter and traversal of the guidewire through the vasculature" (Samson, col. 5, ll. 30-36).

20. Samson's Figure 2 is reproduced below:

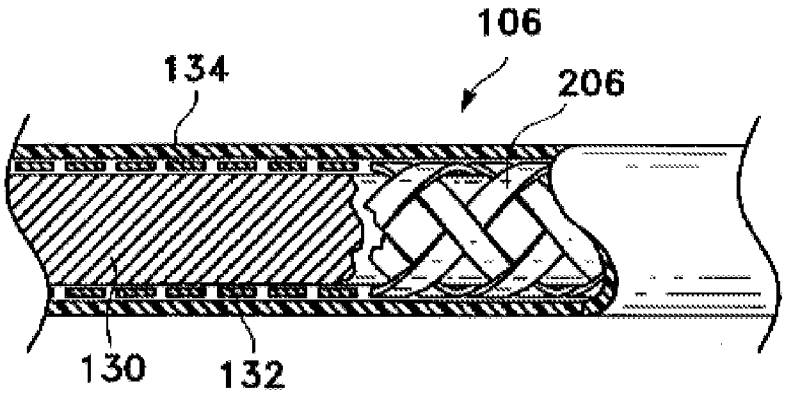

FIG. 2

Figure 2 "shows a partial cutaway of the middle section of the inventive guidewire (106) showing the core wire (130), a supporting ribbon braid (132), and the polymeric covering (134)" (Samson, col. 5, ll. 59-62).

21. Samson discloses that the ribbons 206 that make up the braid 132 "provide specific physical strengths of various types, e.g., torsional rigidity,

stiffness, kink resistance, composite elasticity, etc. The braid is placed directly upon the wire core and is bonded directly to the core wire body in at least two contact locations" (*id.* at col. 8, l. 63 through col. 9, l. 1).

22. Samson's Figure 4 is reproduced below:

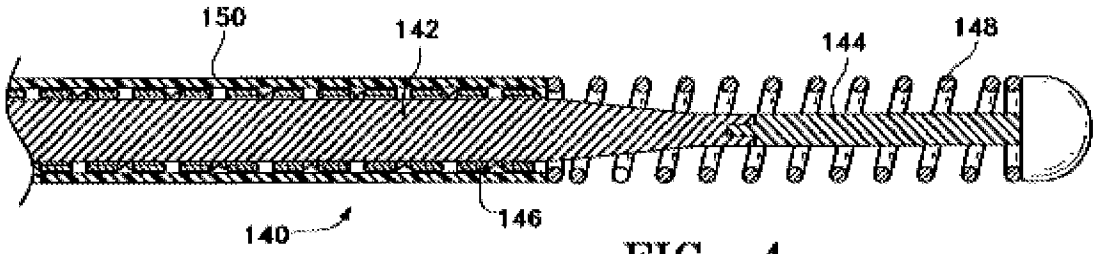

FIG. 4

> FIG. 4 shows a guidewire assembly (140) having a two-part composite core made up of a super-elastic alloy proximal portion (142) and a stainless steel distal section (144). The super-elastic braid (146) provides controlled mechanical support to the super-elastic core wire portion (142). A radio-opaque distal coil (148) and a polymeric covering (150) are also seen in the drawing.

(Samson, col. 7, ll. 54-60.)

23. Dobson discloses medical devices, including guidewires, that have "a helical coil spring in which a length of the wire forming at least some of the spring coils includes an annular layer of radiopaque material surrounding the central cylindrical portion of the spring wire" (Dobson, col. 1, ll. 53-57).

24. Dobson's Figure 3, reproduced below, "is a greatly enlarged sectional view of the coil" (*id.* at col. 2, l. 17):

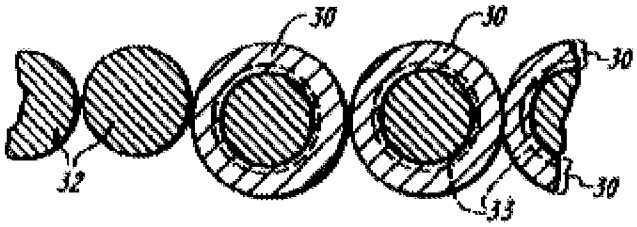

FIG. 3

Figure 3 "shows both annular layer 30 and the central portion 32 of the stainless steel wire that the layer 30 circumferentially surrounds" (*id.* at col. 3, ll. 34-36).

25. Dobson discloses that, in preferred embodiments, the wire's outer radiopaque portion is a thin layer of gold, which is ion-deposited onto a stainless steel inner wire (*id.* at col. 4, ll. 4-16).

26. Dobson discloses that in "other embodiments, dense radiopaque materials other than gold (e.g., platinum, tantalum, tungsten, iridium, rhenium, or an alloy of two or more such materials) may be ion implanted to form the desired increased radiopacity annular layers on the stainless steel spring wire" (*id.* at col. 4, ll. 48-52).

27. The Examiner states that stainless steel has a Young's Modulus "typically ranging between 195-210 GPa" (Ans. 8 (citing App. Br. 16)), and tungsten has a Young's modulus which "typically ranges between 400-410 GPa, as is well known in the art" (*id.*).

Appellant does not dispute these figures.

PRINCIPLES OF LAW

"During examination, the examiner bears the initial burden of establishing a *prima facie* case of obviousness." *In re Kumar*, 418 F.3d 1361, 1366 (Fed. Cir. 2005).

As the Supreme Court pointed out in *KSR Int' l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." Rather, the Court stated:

> [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does* . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 418-419 (emphasis added); *see also id.* at 418 (requiring a determination of "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue") (emphasis added).

While holding that some rationale must be supplied for a conclusion of obviousness, the Supreme Court nonetheless emphasized a flexible approach to the obviousness question, reasoning that the analysis under 35 U.S.C. § 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418; *see also id.* at 421 ("A person of ordinary skill is . . . a person of ordinary creativity, not an automaton.").

Applying these concepts, the Court reaffirmed "that when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)).

Ultimately, therefore, "when the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant inquiry is "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.*

Regarding claim interpretation, the PTO must interpret terms in a claim using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Thus, "[c]laims are not to be read in a vacuum[;] while it is true they are to be given the broadest reasonable interpretation during prosecution, their terms still have to be given the meaning called for by the specification of which they form a part." *In re Royka*, 490 F.2d 981, 984 (CCPA 1974).

However, "while 'the specification [should be used] to interpret the meaning of a claim,' courts must not 'import[ ] limitations from the specification into the claim.' . . . [I]t is improper to 'confin[e] the claims to th[e] embodiments' found in the specification . . . ." *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.,* 415 F.3d 1303, 1323 (Fed. Cir. 2005), citations omitted, bracketed text in internal quotes in original); *see also Sjolund v. Musland*,

847 F.2d 1573, 1581 (Fed. Cir. 1988) ("[W]hile it is true that claims are to be interpreted *in light of* the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims."); *In re Bigio,* 381 F.3d 1320, 1325 (Fed. Cir. 2004) ("[A]bsent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition.").

ANALYSIS

We agree with Appellant that the Examiner erred in concluding that claims 1 and 10 encompass the coiled elements suggested by Samson and Dobson.

Claim 1 recites a medical device that includes a coil formed from a wire having a cross-section in which "the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil."

Thus, for a coiled wire with a rectangular cross section to have a moment of inertia I_x greater than the moment of inertia I_y, the longitudinal walls parallel to the x axis must be shorter than the radial walls parallel to the y axis (*see* FF 4-9). That is, for a wire with a rectangular cross section to meet the requirements of claim 1, the shorter walls of the rectangle must be parallel to the coil's longitudinal axis and the longer walls of the rectangle must be parallel to the coil's radial axis.

In contrast, the ribbons 206 forming the braids 132 coiled around Samson's device are all aligned such that the rectangle's longer walls are parallel to the coil's longitudinal axis (*see* FF 20, 22), an orientation

opposite that required by claim 1. We therefore do not agree with the Examiner that the coiled ribbons of Samson's device meet the requirements of claim 1.

Regarding wires with non-polygonal cross-sections, a wire with an elliptical cross-section would meet the requirements of claim 1 if the ellipse were aligned such that the longer walls were aligned along the coil's radial axis, and the shorter walls were aligned along the longitudinal axis (*see* FF 10, 11). However, the Examiner has not explained how any of Samson's coiled wires with non-polygonal cross-sections, such as coil 148 (FF 22), meet that requirement.

Rather, Samson's non-polygonal coiled wires all appear to be circular in cross-section, which would not meet claim 1, since the distance between the centroid and the wire's edge along the x and y axes would be identical, therefore resulting in an identical moment of inertia, as defined in Appellant's Specification (*see* FF 7). Also, Dobson's composite coiled wires do not remedy this deficiency, as they are also circular (*see* FF 24).

The Examiner argues that Samson's coiled wires meet the requirements of claim 1 because they have polygonal cross sections with "more material . . . distributed away from the longitudinal axis (the x-axis) without less material being distributed away from the radial axis (the y-axis)" (Ans. 5-6 (citing App. Br. 13-15)). We are not persuaded by this argument.

The Examiner appears to be basing this claim interpretation on an erroneous understanding of a statement in the Appeal Brief. Appellant states on page 13 of the Appeal Brief, that, "[i]n order to change the ratio [of the moments of inertia I_x and I_y], more material would need to be moved away

from the x-axis (longitudinal axis) without moving the same or greater amount of material away from the y-axis (radial axis), or vise versa" (App. Br. 13).

However, as is evident from the discussion above, Appellant's Specification makes it clear that, for a wire to meet the requirements of claim 1, there must be less material along the longitudinal, or x axis, and more material along the radial, or y axis (*see* FF 3-11). As discussed above, Samson's coiled wires do not have the required orientation, and Dobson does not remedy this deficiency in Samson.

In sum, we reverse the Examiner's rejection of claim 1, and its dependent claims 2, 5, 7, and 9, as being obvious in view of Samson and Dobson. Because the guidewire of claim 10 requires a coil with the properties recited in claim 1, we also reverse the Examiner's obviousness rejection of claim 10 and its dependent claims 11, 14, 16, and 18.

Appellant's arguments do not persuade us, however, that the Examiner erred in concluding that claims 19 and 26 encompass the coiled elements of Dobson's device.

Claim 19 recites a medical device that has a coiled composite wire made from a first material having a first Young's Modulus at the cross-sectional centroid and a second material having a second Young's Modulus further away from the centroid along the wire's radial axis. Claim 19 also requires the second Young's Modulus to be greater than the first Young's Modulus. That is, the material away from the centroid must be stiffer than the material at the centroid (*see* FF 15).

Appellant argues that Dobson fails to meet the requirements of claim 19 because Dobson uses a stainless steel inner wire coated with gold, the

gold having a much lower Young's Modulus than stainless steel (App. Br. 16). We are not persuaded by this argument.

As the Examiner points out, Dobson teaches that tungsten may be used as the outer radiopaque coating for its wire, instead of gold (FF 26). As the Examiner further points out, and Appellant does not dispute, the Young's Modulus of tungsten is greater than stainless steel (FF 27).

Thus, Dobson teaches a coiled wire with a first material, stainless steel, at the wire's cross-sectional centroid, and a stiffer second material, tungsten, away from the centroid along the radial axis (FF 24, 26). We therefore agree with the Examiner that Dobson suggests using, in a medical device, a coiled wire with the properties required by claim 19.

Appellant argues that using materials with the properties recited in claim 19 "may give the coil increased torsional rigidity without sacrificing the flexibility of the coil, thereby increasing the torqueability/flexibility ratio of the coil" (Reply Br. 7 (citing Spec. 15:16-28)). In contrast, Appellant argues, "[t]he multi-layer wire of the spring 14 taught in Dobson does not possess the notable characteristics of the claimed coil. Namely, material distribution around the centroid of the cross-section of the spring 14 is equal in all directions. Thus, the torqueability/flexibility ratio of the spring 14 is not increased" (*id.*).

We are not persuaded by this argument. We note the Specification's assertion of the torqueability/flexibility advantages of using coiled wires in which material is removed from the x axis "without moving the same amount of material away from the centroid and y-axis" (Spec. 15). However, the Specification states that these advantages inhere from having a greater moment of inertia about the x axis than the y axis (*see id.*).

In contrast to claim 1, however, claim 19 does not require the wire to have a cross section in which the moment of inertia along the x axis is greater than the moment of inertia along the y axis. Nor does claim 19 recite any limitation directed to torqueability or flexibility. Rather, claim 19 merely requires the wire to have a stiffer material away from the centroid along the radial axis, and does not exclude the stiffer material from being present along the longitudinal axis.

Claim 19 therefore encompasses wires with symmetrical cross-sections, including Dobson's symmetrical composite wire. Accordingly, we are not persuaded that the Examiner failed to make a prima facie case of obviousness with respect to claim 19.

Thus, we affirm the Examiner's rejection of claim 19 as obvious in view of Samson and Dobson. Because they were not argued separately, claims 25, 26, and 32 fall with claim 19. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellant separately argues that claims 21, 22, 28, and 29 are unobvious over the cited references (App. Br. 17). We select claim 22 as representative of the argued group of claims. *See* 37 C.F.R. 41.37(c)(1)(vii).

Claim 22 recites "[t]he medical device according to claim 19, wherein the wire cross-section is a rectangular shape."

Appellant argues that the Examiner misinterpreted the rectangular ribbons constituting the braid portion 132 of Samson's as being part of the coil 112 or 148 (App. Br. 17-18; *see also* FF 18-22). Appellant's argument does not persuade us that the Examiner's conclusion of obviousness is in error.

Dobson discloses the suitability of providing a coiled wire on an intraluminal medical device, such as a guidewire, with a radiopaque coating

to make the device detectable when inserted (*see* FF 23). Samson discloses that such detectability is also desirable on its devices (FF 19). In view of these teachings we conclude that a person of ordinary skill in the art would have considered it obvious to include a radiopaque coating on rectangular cross-sectioned wires, such as those used on Samson's device, to allow detection of the wire while inserted in a patient.

We therefore affirm the Examiner's rejection of claim 22 as being obvious over Samson and Dobson. Because they were not argued separately, claims 21, 28, and 29 fall with claim 22. *See* 37 C.F.R. § 41.37(c)(1)(vii).

SUMMARY

We reverse the Examiner's rejection of claims 1, 2, 5, 7, 9-11, 14, 16, and 18, under 35 U.S.C. § 103(a) as being unpatentable over Samson in view of Dobson.

However, we affirm the Examiner's rejection of claims 19, 21, 22, 25, 26, 28, 29, and 32, as being obvious over those references.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

cdc

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